

U.S. APPLICATION NO. 10/606,409  
ATTORNEY DOCKET NO. 64118.000141

### **III. REMARKS/ARGUMENTS**

#### **A. STATUS OF THE CLAIMS**

Claims 1-17 are pending. Claims 1-17 stand rejected. Applicants respectfully request reconsideration of the rejections of claims 1-17 for at least the following reasons.

#### **B. SUMMARY OF TELEPHONE CONFERENCES**

Applicants would like to thank Examiner Reimers for the courtesy extended to Applicants' representative during telephone calls on September 26, 2006 and October 4, 2006. Due to the posture of this application, in order to fully consider Applicants' positions, Examiner Reimers suggested that Applicants file a Response. Applicants' representative agreed. No other agreements were reached.

#### **C. CLAIM REJECTIONS UNDER 35 U.S.C. § 102(e)**

Claims 1-17 stand rejected as allegedly anticipated by U.S. Patent No. 6,740,090 to Cragg *et al.* ("Cragg"). Specifically, the Office Action again asserts:

Cragg discloses a device comprising: a) a proximal end (end at 416); b) a distal end comprising a cutting cap (420) comprising a plurality of deformable blades (424); and c) a shaft (404) between the proximal end and the cutting cap; where the plurality of deformable blades can cut material in a space when the blades not deformed (FIG. 32), after accessing the space through a passage while the blades are deformed (FIG. 30); and where the passage has a smaller cross-sectional area than the lateral cross-sectional area of the undeformed blades while the blades are cutting the material (FIG. 29); where the shaft is flexible (Column 18 lines 17-30); further comprising an axial guidewire lumen between the proximal end and the distal end (Column 17, line 65-Column 18, line 1).

Office Action, Pages 2-3 (emphasis added). In response to this rejection, Applicants previously argued that Cragg did not disclose at least the claimed

U.S. APPLICATION No. 10/606,409  
ATTORNEY DOCKET No. 64118.000141

deformable blades. This is because Cragg discloses cutting tool bands 424<sub>1</sub> to 424<sub>n</sub> that cannot cut material while not deformed, but instead can cut material when they are bowed. Similarly, Cragg's cutting tool bands 424<sub>1</sub> to 424<sub>n</sub> do not access a space when deformed, but instead access a space while in their normal (straight) position.

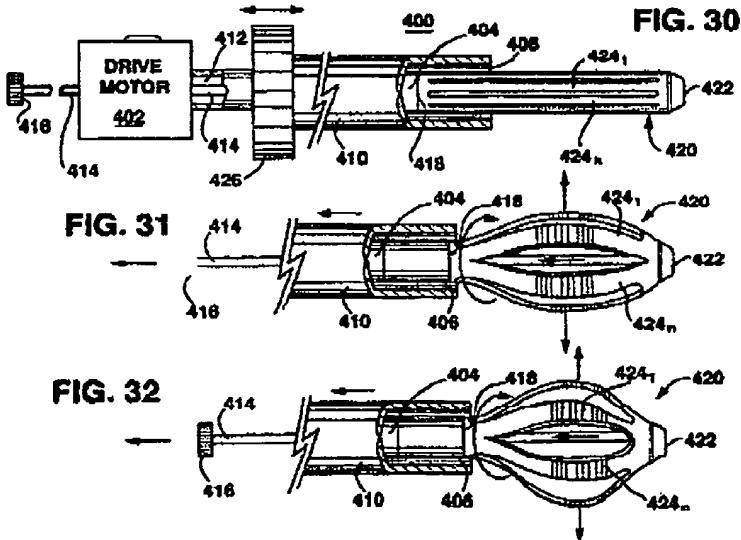
The Office Action did not find these distinctions persuasive, apparently because the Office Action considers the structural limitations "the plurality of deformable blades can cut material in a space when the blades not deformed, after accessing the space through a passage while the blades are deformed" and "the passage has a smaller cross-sectional area than the lateral cross-sectional area of the undeformed blades while the blades are cutting the material" to be statements of intended use. Office Action, Page 3. In support of its contention, the Office Action cites Ex parte Masham, 2 USPQ2d 1647 (Bd. Pat. App. & Inter. 1987). In Masham, the preamble for the claim recited that the apparatus was "for mixing flowing developer material" and the body of the claim recited "means for mixing ..., said mixing means being stationary and completely submerged in the developer material." The claim was rejected over a reference which taught all the structural limitations of the claim, but was only partially submerged in the developer material. The Board held that the amount of submersion is immaterial to the structure of the mixer and thus the claim was properly rejected.

The present situation is distinguishable from Masham. The claim elements at issue, "the plurality of deformable blades can cut material in a space when the blades not deformed, after accessing the space through a passage while the blades are deformed" and "the passage has a smaller cross-sectional area than the lateral cross-sectional area of the undeformed blades while the blades are cutting the material" are structural limitations. These elements further specify the structure of

U.S. APPLICATION NO. 10/606,409  
ATTORNEY DOCKET NO. 64118.000141

the "deformable blades" and do not address the intended use of the claimed "enucleation device." For example, the structure of the deformable blades must be such that the blades cut material when they are not deformed (see, e.g., Appl'n, Figs. 12-13) and that the blades can pass through a passage when the blades are deformed (see, e.g., Appl'n, Fig. 11). These structural elements distinguish the claimed device from that disclosed by Cragg, which discloses cutting tool bands 424<sub>1</sub> to 424<sub>n</sub> that cannot cut material while not deformed, but instead can cut material when they are bowed. Similarly, Cragg's cutting tool bands 424<sub>1</sub> to 424<sub>n</sub> do not access a space when deformed, but instead access a space while in their normal (straight) position.

The Office Action alleges that "the sharp edges of the plurality of blades, 424, can cut material in a space when the blades are deformed (see figures 30-32 and column 18, lines 64-66). For convenience, Applicants are reproducing these figures below:



U.S. APPLICATION NO. 10/606,409  
ATTORNEY DOCKET NO. 64118.000141

Cragg describes these figures as follows:

The cutting head 420 is formed of a thin flexible metal tube that is slit lengthwise into a number N cutting tool bands 424<sub>1</sub> to 424<sub>n</sub>. The N cutting tool bands 424<sub>1</sub> to 424<sub>n</sub> are spring-like and normally are straight as depicted in FIG. 30. The recess forming tool 400 is inserted through the posterior or anterior TASIF axial bore 22 or 152 to a selected site, e.g., the cephalad end within the most cephalad lumbar vertebral body, in the configuration depicted in FIG. 30.

Then, pull wire 414 is pulled proximally from proximal manipulator 416 and fixed at a first retracted position to commence counter boring the recess within the soft spongy cancellous bone of the vertebral body. The pull wire 414 pulls the cutting tool distal end 422 proximally causing the N cutting tool bands 424<sub>1</sub> to 424<sub>n</sub> to bow outward as shown in FIG. 31. Then the pull wire proximal manipulator 416 is locked in position, e.g., by a chuck mechanism, and the drive motor 402 is energized to rotate the cutting head 420 through mutual rotation of the drive shaft 404 and the pull wire 414. The sharp edges of the cutting tool bands 424<sub>1</sub> to 424<sub>n</sub> cut away the surrounding vertebral bone, and the cutting tool bands 424<sub>1</sub> to 424<sub>n</sub> expand further outward until the rotation is halted. The pull wire 414 can be pulled back more proximally and set again to expand the cutting tool bands 424<sub>1</sub> to 424<sub>n</sub> outward further as shown in FIG. 32. If further enlargement of the recess is desired.

Cragg, Col. 18, ll. 31-55 (emphasis added). Therefore, Cragg's cutting tool bands "normally are straight" (e.g., their undeformed state) and are not disclosed as cutting. Only when the cutting tool bands "bow outward" (e.g., their deformed state) are the cutting bands disclosed as "cut[ting] away the surrounding vertebral bone."

The Office Action also cites column 18, lines 64-66 allegedly in support of its proposition that the cutting bands of Cragg can cut material in their undeformed state. However, column 18, lines 64-66 merely state: "The cutting tool 400 can be varied in many respects, e.g., by changing the shape, length, number and materials

U.S. APPLICATION NO. 10/606,409  
ATTORNEY DOCKET NO. 64118.000141

used for the cutting tool bands 424<sub>1</sub> to 424<sub>n</sub>.” Cragg, col. 18, ll. 64-66. This passage does not support the Office Action’s assertion.

Further, with regard to claim 11, Cragg simply does not disclose the steps of “deforming the blades to fit through the passage,” “advancing the enucleation device through the passage until the cutting cap passes into the space, thereby allowing the blades to expand to their undeformed shape;” and “actuating the enucleation device, thereby effecting cutting of the material.” As discussed above, Cragg discloses precisely the opposite. Therefore, Cragg does not disclose the method of claim 11.

Therefore, because Cragg fails to disclose each and every element of independent claims 1, 4, and 11, as well as all claims dependent thereon, Applicants respectfully request that this rejection be withdrawn.

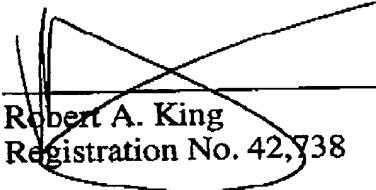
#### IV. CONCLUSION

Applicants respectfully submit that the application is in condition for allowance. Applicants believe that no fees are necessary in connection with the filing of this document. In the event any fees are necessary, please charge such fees, including fees for any extensions of time, to the undersigned’s Deposit Account No. 50-0206. Should any outstanding issues remain, the Examiner is invited to telephone the undersigned at the number listed below.

U.S. APPLICATION NO. 10/606,409  
ATTORNEY DOCKET NO. 64118.000141

Respectfully submitted,  
**HUNTON & WILLIAMS LLP**

By:

  
Robert A. King  
Registration No. 42,738

Dated: October 4, 2006

Hunton & Williams LLP  
1900 K Street, N.W., Suite 1200  
Washington, D.C. 20006-1109  
(202) 955-1500 (telephone)  
(202) 778-2201 (facsimile)